

REMARKS

Reconsideration of the present application, as amended, is respectfully requested.

Claims 24-45 are cancelled and replaced by new claims 46-69. New claim 46 more particularly defines the claimed delivery device. In the Advisory Action, the Examiner has taken the position that changing the phrase, “uniform layer” to “uniform film layer” may represent impermissible new matter. Applicant respectfully disagrees. The context provided by the examples makes it perfectly clear that the claimed invention is a device that is a film. A film is art understood to be thin. When reading, e.g., the last two paragraphs of Example 2 of the specification, it is clear that:

[0052] (i) casting the product of (h) onto a release liner at 15-mil thickness; and,
[0053] (j) drying the product of (i) in an oven until **the film is uniform** and not-tacky (about 10 minutes).

It is urged that while the exemplified uniform film layer is cast at 15-mil, the meaning of the examples and the remainder of the disclosure fully enables (including with written description) and supports the wording of new claim 46, et seq. without limiting the claims to 15-mil.

In addition, new claim 46 now recites concentration ranges for polyvinyl pyrrolidone as a filmogenic polymer, and polyethylene glycol as a plasticizer, based on the proportions provided by Table 2 and examples 1-8. New claims 47-54 provide even greater specificity in components and proportions, supported by Examples 1-8, as follows.

Claim #	Support
47	Example 1
48	Example 2
49	Example 3
50	Example 4
51	Example 5
52	Example 6
53	Example 7
54	Example 8

The remaining new claims are based on cancelled claims 10-24, while being conformed to new claim 46. No new matter is added.

THE CLAIMED INVENTION IS NOVEL UNDER 35 U.S.C. 102(e)

At item 2 of the previous Office Action, the Examiner has maintained the rejection of

claims 24-34, 35-40 and 43-45 under 35 U.S.C. 102(e) as allegedly anticipated by Biedermann et al. (U.S. 5,980,921) (hereinafter "Biedermann"). The Examiner has reiterated the position that Biedermann describes a topical composition "formulated as a cleansing composition in the form of bath gels, liquid, shampoos, hair tonic, pastes and mousses..." that also can comprise a "film forming polymer that is not tacky..." At page 4 of the Office Action, under the heading, "*Response to Arguments*," the Examiner takes the position that,

The physical form of the Biedermann cleansing formulation is "toilet bars, liquids, shampoos, bath gels, hair conditioners, hair tonics, pastes, or mousses. *Toilet bars* are most preferred since this is the form of cleansing agent most commonly used to wash the skin," (column 6, lines 41-44).

At the top of page 5 of the Office Action, the Examiner further states that:

Regarding applicant's argument that Biedermann's formulation is not a dry uniform layer, it is noted that one of the physical forms of Biedermann's formulation is a toilet bar (column 6, line 41) and a toilet bar which is used as a cleansing agent is .dry and of uniform layer such that applicant's claim to a broad water-dissolvable, non-tacky and dry uniform layer reads on Biedermann's toilet bar.

Applicants respectfully disagree. To begin, the rejected claims are now cancelled, thus obviating this ground of rejection. However, in the interest of expeditious prosecution, the following details why the new claims novel in view of Biedermann.

In order to anticipate a claimed invention, a reference must describe each and every element of the invention as claimed. Claim 46 now recites:

A delivery device comprising a uniform mixture of a filmogenic polymer and an effective dose of an active substance, wherein the delivery device comprises a single uniform film layer which is non-tacky and which dissolves onto a wetted skin tissue or mucosal epithelial tissue of a subject when applied thereto, wherein the delivery device comprises, by dry weight, from 78 to 86 wt% of polyvinyl pyrrolidone as a filmogenic polymer and from 0.9 to 5.5 wt% of polyethylene glycol as a plasticizer.

The claimed invention provides a "delivery device" that includes a "dry uniform film layer," that is "suitable for application toa subject." The dry uniform film layer is dissolvable upon application onto a wetted skin tissue..." It is submitted that claim 46 excludes a liquid, cream or toilet bar as described by Biedermann. A film is defined, *inter alia*, by the Webster's Ninth New Collegiate Dictionary¹ as, "a thin covering or coating" or "an exceedingly thin layer."

¹ Webster's Ninth New Collegiate Dictionary, page 463, Copyright 1988. Previously made of record.

That this is the meaning of the term in the present application is made clear by the examples, that describe casting exemplary films in a 15-mil thickness.²

It is respectfully submitted that Biedermann fails to describe or suggest any such delivery device. The Examiner has taken the position in the recently mailed Advisory Action that the amended claims that were not entered After Final might read on a dry surface of a toilet bar. It is respectfully submitted that this position would not be shared by the ordinary artisan, who would not confuse the surface of a *solid* toilet bar, as described by Biedermann, with the instantly claimed device comprising a “single uniform film layer,” since a toilet bar would comprise a plurality of such film layers (assuming *arguendo* that a toilet bar comprises *any* film layers).

In addition, while the Biedermann composition may hypothetically form a dry film after contact with skin, it is urged that such a film formed on the skin, after application, is not a dry uniform film layer that is suitable for applicable to the skin, as required by claim 24, et seq.

Further, it is respectfully urged that there is no showing of record that Biedermann teaches or suggests the composition of claim 46, with the specific ranges for polyvinyl pyrrolidone and polyethylene glycol, in a single composition.

For all of these reasons, reconsideration and withdrawal of this ground of rejection is respectfully requested.

THE CLAIMED INVENTION IS NONOBVIOUS UNDER 35 U.S.C. 103(a)

At item 5 of the Office Action, the rejection of claims 35 and 42 under 35 U.S.C. 103(a) as allegedly obvious over Biedermann, taken alone, is maintained. The Examiner apparently takes the position that the toilet bar described by Biedermann falls within the scope of the claims 35 and 42, without the necessity of pointing to any additional reference to remedy the clear deficiencies of Biedermann as a reference under 35 U.S.C. 102, as discussed above.

Applicants respectfully disagree. Claims 35 and 42 are cancelled, thus obviating this ground of rejection.

For all of these reasons, reconsideration and withdrawal of this ground of rejection is respectfully requested.

² E.g., Example 2; 15 mils is 15/1000th of an inch.

CONCLUSION

This response is being filed with a Petition for a two-month extension of time, and the required petition fee. No fee is believed to be due for additional claims. If, on the other hand, it is determined that any fees are due or any overpayment has been made, the Commissioner is hereby authorized to debit or credit such sum to deposit account 02-2275. Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.

In view of the actions taken and arguments presented, it is respectfully submitted that each of the matters raised by the Examiner has been addressed by the present amendment and that the present application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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